March 5, 2004
Re: Manufacturer Recalls of Rapid Cryptosporidium/Giardia assay kits

Dear Colleague,

Recent reported increases in the number of *Cryptosporidium* cases might be due to false positive results according to the March 4, 2004 MMWR. Since January 1, 2004, a total of 14 cases of cryptosporidiosis were reported to the Colorado Department of Public Health and Environment. During the previous 7 years, an average number of three cases were reported during January-February. In eight of the 14 patients, rapid testing was performed by using the ImmunoCard STAT!® Cryptosporidium/Giardia Rapid Assay (Meridian Bioscience, Inc., Cincinnati, Ohio). This assay is a solid-phase qualitative immunochromatographic assay designated to detect and distinguish between *Giardia intestinalis (lamblia)* and *Cryptosporidium parvum* in aqueous extracts of human fecal specimens. Seven of these samples were tested by using lot no. 081093 (expires August 11, 2004). Of the seven samples that initially tested positive for *Cryptosporidium* with this lot number, four were retested by using other, more specific tests. One patient sample was positive by direct microscopy, one was negative by direct microscopy, and two were negative by direct fluorescent-antibody testing, suggesting that results for three of the four samples were false-positive. The results of testing for *Giardia intestinalis (lamblia)* with these kits are unclear. Several other states have noted increases in the number of reported cryptosporidiosis cases that also might be associated with use of these rapid assays. Meridian Bioscience, Inc., has notified the laboratories who purchase these kits, and has voluntarily recalled two lots (lot numbers 081077 expires July 11, 2004; and 081093 expires August 11, 2004) of the ImmunoCard STAT! Rapid assay for the detection of Cryptosporidium and Giardia. The CDC recommends reconfirmation of positive test results obtained from these lot numbers.

We have also been notified that Becton Dickinson will issue a recall for BD ColorPAC Giardia/Cryptosporidium Rapid Assay Test Kit, Product Number 240909, lot number 071093.

Laboratories are required by law to report *Cryptosporidium* positive results to the local health department within three working days. Laboratories that are unable to perform confirmatory testing of rapid assays for *Cryptosporidium* can submit stool samples in formalin to the Michigan Department of Community Health for testing. Unpreserved stools, or those submitted in other transport media, are unacceptable for this procedure. Please clearly mark the requisition as **confirmatory testing for Cryptosporidium.** Information on MDCH testing services is available on our website
http://www.michigan.gov/mdch (Click on Providers, Lab Services).

Laboratories using rapid assays for these or any other agents may want to monitor their rate of positive results as part of a quality assurance program.

The MMWR article may be viewed at:
http://www.cdc.gov/mmwr/pdf/wk/mm53d304.pdf

If you have further questions, please call Dr. James Rudrik, Microbiology Manager at 517-335-9641.

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